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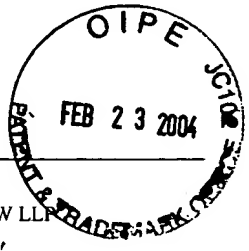
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

On 2-19-04

TOWNSEND and TOWNSEND and CREW LLP

By: Karen Karlin



PATENT
Attorney Docket No.: 015280-382100US
Client Ref. No.: E-009-1999/0-US-03

RECEIVED
MAR 0 2 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

DEAN et al.

Application No.: 09/856,927

Filed: September 19, 2001

For: A NOVEL ATP-BINDING CASSETTE PROTEIN RESPONSIBLE FOR CYTOTOXIN RESISTANCE

Customer No.: 20350

Confirmation No. 6490

Examiner: HUFF, Sheela J.

Technology Center/Art Unit: 1642

Declaration of Michael Dean, Rando Allikmets, Susan Bates, and Antonio Fojo pursuant to 37 C. F. R. §1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Michael Dean, Rando Allikmets, Susan Bates, and Antonio Fojo, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. §1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of our own knowledge are true and statements made on information or belief are believed to be true. Exhibit I is attached hereto and are incorporated herein by reference.

2. At the time this invention was first conceived, we were employees at the National Cancer Institute, located in Frederick, Maryland. All activities described in this Declaration took place in the United States of America.

3. In accordance with 37 C.F.R. §1.131, we state that we completed the claimed invention in the United States prior to February 5, 1998, which is the priority date for U.S. Patent No. 6,313,277 to Ross *et al.*

4. Attached to this Declaration are Exhibit I, the dates on which have been redacted. All redacted dates are prior to February 5, 1998.

5. Conception of the present invention as well as its reduction to practice are evidenced by Exhibit I, which is a copy of a printout containing the polynucleotide sequence of SEQ ID NO:1 and the corresponding amino acid sequence SEQ ID NO:2 of the present application, both in the full length. The codons for the start and termination of the polypeptide are marked in Exhibit I on pages 1 and 4, respectively.

6. As marked in Exhibit I, the polynucleotide sequence in this printout contains 9 additional nucleotides (circled) that are not present in SEQ ID NO:1. As a result, the amino acid sequence translated from the polynucleotide sequence contains a stretch of 40 amino acid residues (highlighted) that is inconsistent with the 37 amino acids from position 565 to position 601 (inclusive) in SEQ ID NO:2. The remaining portions of the polynucleotide sequence and polypeptide sequence of Exhibit I are identical to the corresponding portions of SEQ ID NO:1 and SEQ ID NO:2, respectively. The inclusion of these 9 extra nucleotides, each a part of a nucleotide doublet, triplet, or quadruplet of the same nucleotide, in the polynucleotide sequence was due to a misreading of the DNA sequencing data. This misreading further led to the incorrect amino acid sequence in the highlighted portion.

7. The error of including one or more additional nucleotides of the same kind when reading a doublet, triplet, and the like in DNA sequencing data is common, due primarily to the resolution limit of a polyacrylamide sequencing gel. The interpretation of DNA

sequencing data and the subsequent translation of the encoded amino acid sequence, as shown in Exhibit I, were later corrected, when SEQ ID NO:1 and SEQ ID NO:2 were established for the filing of the present application.

8. In light of the foregoing, it is established that Declarants had in their possession the claimed subject matter of the present invention prior to February 5, 1998.

9. Declarants have nothing further to say.

Dated: 1/30/04 By: _____
Michael Dean, Ph.D.

Dated: _____ By: _____
Rando Allikmets, Ph.D.

Dated: _____ By: _____
Susan Bates, Ph.D.

Dated: _____ By: _____
Antonio Fojo, Ph.D.

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Attachments (Exhibit I: redacted copy of sequencing results)
60075067 V1

sequencing data and the subsequent translation of the encoded amino acid sequence, as shown in Exhibit I, were later corrected, when SEQ ID NO:1 and SEQ ID NO:2 were established for the filing of the present application.

8. In light of the foregoing, it is established that Declarants had in their possession the claimed subject matter of the present invention prior to February 5, 1998.

9. Declarants have nothing further to say.

Dated: _____ By: _____
Michael Dean, Ph.D.

Dated: 01/25/2004 By: _____
Rando Allikmets, Ph.D.

Dated: _____ By: _____
Susan Bates, Ph.D.

Dated: _____ By: _____
Antonio Fojo, Ph.D.

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8. In light of the foregoing, it is established that Declarants had in their possession the claimed subject matter of the present invention prior to February 5, 1998.

9. Declarants have nothing further to say.

Dated: _____ By: _____
Michael Dean, Ph.D.

Dated: _____ By: _____
Rando Allikmets, Ph.D.

Dated: _____ By: _____
Susan Bates, M.D.

Dated: _____ By: _____
Antonio Fojo, Ph.D.
M.D.

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60075067 V1

(Linear) MAP of: 4464.Seq check: 4209 from: 1 to: 2728

From: FCRFV1::ALLIKMET "RANDO ALLIKMETS" 16:10:24.34
To: DEAN
CC:
Subj:
4464 plac clone marathon long fragment forward seq

With 1 enzymes: ECORI

16:12 ..

```
          TTTAGGAACGCACCGTGCACATGCTTGGTGGTCTTGTTAAGTGGAAACTGCTGCTTTAGA
        1 ---------+---------+---------+---------+---------+---------+ 60
          AAATCCTTGCGTGGCACGTGTACGAACCACCAGAACAATTCACCTTTGACGACGAAATCT

a           F  R  N  A  P  C  T  C  L  V  V  L  L  S  G  N  C  C  F  R  -

          GTTTGTTTGGAAGGTCCGGGTGACTCATCCCAACATTTACATCCTTAATTGTTAAAGCGC
       61 ---------+---------+---------+---------+---------+---------+ 120
          CAAACAAACCTTCCAGGCCCACTGAGTAGGGTTGTAAATGTAGGAATTAACAATTTCGCG

a           V  C  L  E  G  P  G  D  S  S  Q  H  L  H  P  *  L  L  K  R  -

          TGCCTCCGAGCGCACGCATCCTGAGATCCTGAGCCTTTGGTTAAGACCGAGCTCTATTAA
      121 ---------+---------+---------+---------+---------+---------+ 180
          ACGGAGGCTCGCGTGCGTAGGACTCTAGGACTCGGAAACCAATTCTGGCTCGAGATAATT

a           C  L  R  A  H  A  S  *  D  P  E  P  L  V  K  T  E  L  Y  *  -

                                  START
          GCTGAAAAGATAAAAACTCTCCAGATGTCTTCCAGTAATGTCGAAGTTTTTATCCCAGTG
      181 ---------+---------+---------+---------+---------+---------+ 240
          CGACTTTTCTATTTTTGAGAGGTCTACAGAAGGTCATTACAGCTTCAAAAATAGGGTCAC

a           A  E  K  I  K  T  L  Q  M  S  S  S  N  V  E  V  F  I  P  V  -

          TCACAAGGAAACACCAATGGCTTCCCCGCGACAGTTTCCAATGACCTGAAGGCATTTACT
      241 ---------+---------+---------+---------+---------+---------+ 300
          AGTGTTCCTTTGTGGTTACCGAAGGGGCGCTGTCAAAGGTTACTGGACTTCCGTAAATGA

a           S  Q  G  N  T  N  G  F  P  A  T  V  S  N  D  L  K  A  F  T  -

          GAAGGAGCTGTGTTAAGTTTTCATAACATCTGCTATCGAGTAAAACTGAAGAGTGGCTTT
      301 ---------+---------+---------+---------+---------+---------+ 360
          CTTCCTCGACACAATTCAAAAGTATTGTAGACGATAGCTCATTTTGACTTCTCACCGAAA

a           E  G  A  V  L  S  F  H  N  I  C  Y  R  V  K  L  K  S  G  F  -

          CTACCTTGTCGAAAACCAGTTGAGAAAGAAATATTATCGAATATCAATGGGATCATGAAA
      361 ---------+---------+---------+---------+---------+---------+ 420
          GATGGAACAGCTTTTGGTCAACTCTTTCTTTATAATAGCTTATAGTTACCCTAGTACTTT

a           L  P  C  R  K  P  V  E  K  E  I  L  S  N  I  N  G  I  M  K  -

          CCTGGTCTCAACGCCATCCTGGGACCCACAGGTGGAGGCAAATCTTCGTTATTAGATGTC
      421 ---------+---------+---------+---------+---------+---------+ 480
          GGACCAGAGTTGCGGTAGGACCCTGGGTGTCCACCTCCGTTTAGAAGCAATAATCTACAG

a           P  G  L  N  A  I  L  G  P  T  G  G  G  K  S  S  L  L  D  V  -
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/

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     TTAGCTGCAAGGAAAGATCCAAGTGGATTATCTGGAGATGTTCTGATAAATGGAGCACCG
481  ---------+---------+---------+---------+---------+---------+ 540
     AATCGACGTTCCTTTCTAGGTTCACCTAATAGACCTCTACAAGACTATTTACCTCGTGGC

a      L  A  A  R  K  D  P  S  G  L  S  G  D  V  L  I  N  G  A  P  -

     CGACCTGCCAATTTCAAATGTAATTCAGGTTACGTGGTACAAGATGATGTTGTGATGGGC
541  ---------+---------+---------+---------+---------+---------+ 600
     GCTGGACGGTTAAAGTTTACATTAAGTCCAATGCACCATGTTCTACTACAACACTACCCG

a      R  P  A  N  F  K  C  N  S  G  Y  V  V  Q  D  D  V  V  M  G  -

     ACTCTGACGGTGAGAGAAAACTTACAGTTCTCAGCAGCTCTTCGGCTTGCAACAACTATG
601  ---------+---------+---------+---------+---------+---------+ 660
     TGAGACTGCCACTCTCTTTTGAATGTCAAGAGTCGTCGAGAAGCCGAACGTTGTTGATAC

a      T  L  T  V  R  E  N  L  Q  F  S  A  A  L  R  L  A  T  T  M  -

     ACGAATCATGAAAAAAACGAACGGATTAACAGGGtcattgaagagttaggtCTGGATAAA
661  ---------+---------+---------+---------+---------+---------+ 720
     TGCTTAGTACTTTTTTTGCTTGCCTAATTGTCCCagtaacttctcaatccaGACCTATTT

a      T  N  H  E  K  N  E  R  I  N  R  V  I  E  E  L  G  L  D  K  -

     GTGGCAGACTCCAAGGTTGGAACTCAGTTTATCCGTGGTGTGTCTGGAGGAGAAAGAAAA
721  ---------+---------+---------+---------+---------+---------+ 780
     CACCGTCTGAGGTTCCAACCTTGAGTCAAATAGGCACCACACAGACCTCCTCTTTCTTTT

a      V  A  D  S  K  V  G  T  Q  F  I  R  G  V  S  G  G  E  R  K  -

     AGGACTAGTATAGGAATGGAGCTTATCACTGATCCTTCCATCTTGTCCTTGGATGAGCCT
781  ---------+---------+---------+---------+---------+---------+ 840
     TCCTGATCATATCCTTACCTCGAATAGTGACTAGGAAGGTAGAACAGGAACCTACTCGGA

a      R  T  S  I  G  M  E  L  I  T  D  P  S  I  L  S  L  D  E  P  -

     ACAACTGGCTTAGACTCAAGCACAGCAAATGCTGTCCTTTTGCTCCTGAAAAGGATGTCT
841  ---------+---------+---------+---------+---------+---------+ 900
     TGTTGACCGAATCTGAGTTCGTGTCGTTTACGACAGGAAAACGAGGACTTTTCCTACAGA

a      T  T  G  L  D  S  S  T  A  N  A  V  L  L  L  L  K  R  M  S  -

     AAGCAGGGACGAACAATCATCTTCTCCATTCATCAGCCTCGATATTCCATCTTCAAGTTG
901  ---------+---------+---------+---------+---------+---------+ 960
     TTCGTCCCTGCTTGTTAGTAGAAGAGGTAAGTAGTCGGAGCTATAAGGTAGAAGTTCAAC

a      K  Q  G  R  T  I  I  F  S  I  H  Q  P  R  Y  S  I  F  K  L  -

     TTTGATAGCCTCACCTTATTGGCCTCAGGAAGACTTATGTTCCACGGGCCTGCTCAGGAG
961  ---------+---------+---------+---------+---------+---------+ 1020
     AAACTATCGGAGTGGAATAACCGGAGTCCTTCTGAATACAAGGTGCCCGGACGAGTCCTC

a      F  D  S  L  T  L  L  A  S  G  R  L  M  F  H  G  P  A  Q  E  -

     GCCTTGGGATACTTTGAATCAGCTGGTTATCACTGTGAGGCCTATAATAACCCTGCAGAC
1021 ---------+---------+---------+---------+---------+---------+ 1080
     CGGAACCCTATGAAACTTAGTCGACCAATAGTGACACTCCGGATATTATTGGGACGTCTG

a      A  L  G  Y  F  E  S  A  G  Y  H  C  E  A  Y  N  N  P  A  D  -
```

```
     TTCTTCTTGGACATCATTAATGGAGATTCCACTGCTGTGGCATTAAACAGAGAAGAAGAC
1081 ---------+---------+---------+---------+---------+---------+ 1140
     AAGAAGAACCTGTAGTAATTACCTCTAAGGTGACGACACCGTAATTTGTCTCTTCTTCTG

a    F  F  L  D  I  I  N  G  D  S  T  A  V  A  L  N  R  E  E  D  -

     TTTAAAGCCACAGAGATCATAGAGCCTTCCAAGCAGGATAAGCCACTCATAGAAAAATTA
1141 ---------+---------+---------+---------+---------+---------+ 1200
     AAATTTCGGTGTCTCTAGTATCTCGGAAGGTTCGTCCTATTCGGTGAGTATCTTTTTAAT

a    F  K  A  T  E  I  I  E  P  S  K  Q  D  K  P  L  I  E  K  L  -

     GCGGAGATTTATGTCAACTCCTCCTTCTACAAAGAGACAAAAGCTGAATTACATCAACTT
1201 ---------+---------+---------+---------+---------+---------+ 1260
     CGCCTCTAAATACAGTTGAGGAGGAAGATGTTTCTCTGTTTTCGACTTAATGTAGTTGAA

a    A  E  I  Y  V  N  S  S  F  Y  K  E  T  K  A  E  L  H  Q  L  -

     TCCGGGGGTGAGAAGAAGAAGAAGATCACAGTCTTCAAGGAGATCAGCTACACCACCTCC
1261 ---------+---------+---------+---------+---------+---------+ 1320
     AGGCCCCCACTCTTCTTCTTCTTCTAGTGTCAGAAGTTCCTCTAGTCGATGTGGTGGAGG

a    S  G  G  E  K  K  K  K  I  T  V  F  K  E  I  S  Y  T  T  S  -

     TTCTGTCATCAACTCAGATGGGTTTCCAAGCGTTCATTCAAAAACTTGCTGGGTAATCCC
1321 ---------+---------+---------+---------+---------+---------+ 1380
     AAGACAGTAGTTGAGTCTACCCAAAGGTTCGCAAGTAAGTTTTTGAACGACCCATTAGGG

a    F  C  H  Q  L  R  W  V  S  K  R  S  F  K  N  L  L  G  N  P  -

     CAGGCCTCTATAGCTCAGATCATTGTCACAGTCGTACTGGGACTGGTTATAGGTGCCATT
1381 ---------+---------+---------+---------+---------+---------+ 1440
     GTCCGGAGATATCGAGTCTAGTAACAGTGTCAGCATGACCCTGACCAATATCCACGGTAA

a    Q  A  S  I  A  Q  I  I  V  T  V  V  L  G  L  V  I  G  A  I  -

     TACTTTGGGCTAAAAAATGATTCTACTGGAATCCAGAACAGAGCTGGGGTTCTCTTCTTC
1441 ---------+---------+---------+---------+---------+---------+ 1500
     ATGAAACCCGATTTTTTACTAAGATGACCTTAGGTCTTGTCTCGACCCCAAGAGAAGAAG

a    Y  F  G  L  K  N  D  S  T  G  I  Q  N  R  A  G  V  L  F  F  -

     CTGACGACCAACCAGTGTTTCAGCAGTGTTTCAGCCGTGGAACTCTTTGTGGTAGAGAAG
1501 ---------+---------+---------+---------+---------+---------+ 1560
     GACTGCTGGTTGGTCACAAAGTCGTCACAAAGTCGGCACCTTGAGAAACACCATCTCTTC

a    L  T  T  N  Q  C  F  S  S  V  S  A  V  E  L  F  V  V  E  K  -

     AAGCTCTTCATACATGAATACATCAGCGGATACTACAGAGTGTCATCTTATTTCCTTGGA
1561 ---------+---------+---------+---------+---------+---------+ 1620
     TTCGAGAAGTATGTACTTATGTAGTCGCCTATGATGTCTCACAGTAGAATAAAGGAACCT

a    K  L  F  I  H  E  Y  I  S  G  Y  Y  R  V  S  S  Y  F  L  G  -

     AAACTGTTATCTGATTTATTACCCATGAGGATGTTACCAAGTATTATATTTACCTGTATA
1621 ---------+---------+---------+---------+---------+---------+ 1680
     TTTGACAATAGACTAAATAATGGGTACTCCTACAATGGTTCATAATATAAATGGACATAT

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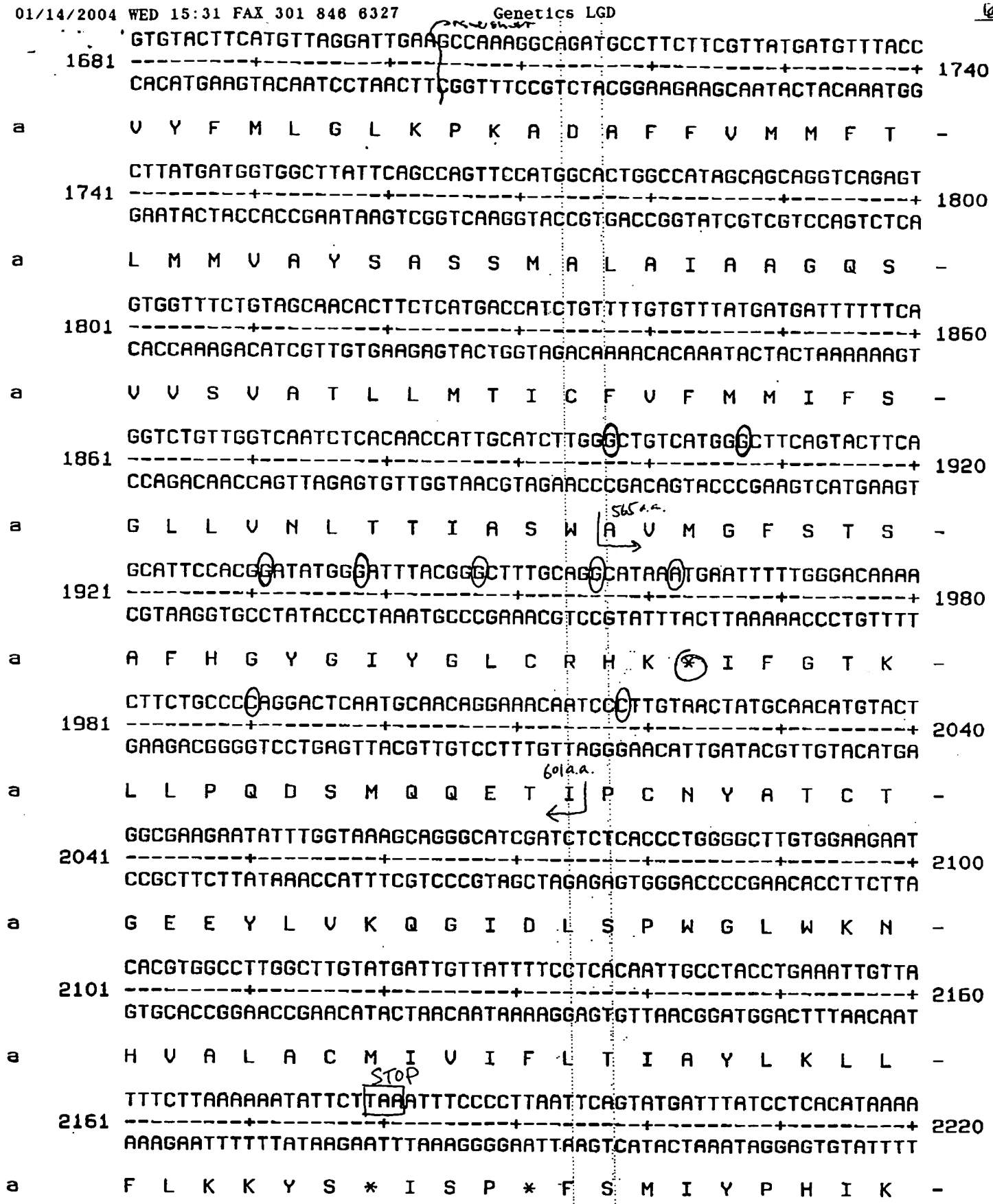
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1681
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1740
a V Y F M L G L K P K A D A F F V M M F T -
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1741
GAATACTACCACCGAATAAGTCGGTCAAGGTACCGTGACCGGTATCGTCGTCCAGTCTCA
1800
a L M M V A Y S A S S M A L A I A A G Q S -
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1801
CACCAAAGACATCGTTGTGAAGAGTACTGGTAGACAAAACACAAATACTACTAAAAAAGT
1860
a V V S V A T L L M T I C F V F M M I F S -
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1861
CCAGACAACCAGTTAGAGTGTTGGTAACGTAGAACCCGACAGTACCCGAAGTCATGAAGT
1920
a G L L V N L T T I A S W A V M G F S T S -
565 a.a.
GCATTCCACGGATATGGGATTTACGGGCTTTGCAGGCATAAATGAATTTTTGGGACAAAA
1921
CGTAAGGTGCCTATACCCTAAATGCCCGAAACGTCCGTATTTACTTAAAAACCCTGTTTT
1980
a A F H G Y G I Y G L C R H K * I F G T K -
CTTCTGCCCCAGGACTCAATGCAACAGGAAACAATCCCTTGTAACTATGCAACATGTACT
1981
GAAGACGGGGTCCTGAGTTACGTTGTCCTTTGTTAGGGAACATTGATACGTTGTACATGA
2040
601 a.a.
a L L P Q D S M Q Q E T I P C N Y A T C T -
GGCGAAGAATATTTGGTAAAGCAGGGCATCGATCTCTCACCCTGGGGCTTGTGGAAGAAT
2041
CCGCTTCTTATAAACCATTTCGTCCCGTAGCTAGAGAGTGGGACCCCGAACACCTTCTTA
2100
a G E E Y L V K Q G I D L S P W G L W K N -
CACGTGGCCTTGGCTTGTATGATTGTTATTTTCCTCACAATTGCCTACCTGAAATTGTTA
2101
GTGCACCGGAACCGAACATACTAACAATAAAAGGAGTGTTAACGGATGGACTTTAACAAT
2160
a H V A L A C M I V I F L T I A Y L K L L -
STOP
TTTCTTAAAAAATATTCTTAAATTTCCCCTTAATTCAGTATGATTTATCCTCACATAAAA
2161
AAAGAATTTTTTATAAGAATTTAAAGGGGAATTAAGTCATACTAAATAGGAGTGTATTTT
2220
a F L K K Y S * I S P * F S M I Y P H I K -